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U.S. Patent and Trademark Office  
Alexandria, VA 22313-1450

Group Art Unit: 3761

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Application No.: 09/837714

First Named Inventor: Japuntich, Daniel A.

Title: Method of Making a Filtering Face Mask that has an Exhalation Valve

Case No.: 48317US032

Attachments: Reply Brief in triplicate

32692

Customer Number

Patent  
Case No.: 48317US032

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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DEC 02 2003

First Named Inventor: JAPUNTICH, DANIEL A.

Application No.: 09/837714

Group Art Unit: 3761

Filed: April 18, 2001

Examiner: Aaron J. Lewis

Title: METHOD OF MAKING A FILTERING FACE MASK THAT HAS AN  
EXHALATION VALVE

OFFICIAL

**REPLY BRIEF**Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## CERTIFICATE OF TRANSMISSION

To Fax No.: 703-872-9306  
I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent  
and Trademark Office on:December 2, 2003  
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Signed by: Susan M. Decko

Dear Sir:

Applicants submit this Reply Brief in response to the Examiner's Answer mailed October 3, 2003. Applicants respectfully dissent from a number of positions taken by the Examiner. Each of the Examiner's positions is reproduced below in quotes, followed by applicants' rebuttal argument.

**1. Examiner's Answer at paragraph bridging pages 9 and 10**

"The Castiglione affidavit contends that the valve flap of Simpson et al. must rely of negative inhalation pressure to maintain a closed position is disagreed with because there is no disclosure in Simpson et al. which suggests such a requirement."

**Applicants' Response:**

The Examiner has erred in interpreting the scope and content of Simpson. There are, in fact, three particular disclosures that show why the Simpson flap is not pressed towards the seal surface under any orientation of its valve.

Firstly, the construction Simpson valve itself shows that there is no preload or bias placed on the flap:

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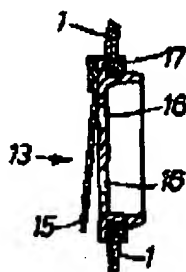


FIG. 2.

As the Board can note, the flap-retaining surfaces is in direct alignment with the seal surface, and there is no other instrument that causes the flap to be pressed towards the seal surface. Therefore, when the valve is inverted, gravity will act upon flap 15 to force it downward. The valve flap — if made from a conventional flap material, which we must assume it is since the patent does not disclose otherwise — will then droop away from the seal surface.

Secondly, Simpson indicates that its valve can leak in the paragraph set forth on page 1, lines 58-64 in the specification:

To prevent inhalation of harmful atmosphere owing to leakage of the or each valve, the valve may be provided with an antechamber so arranged that, if the valve does leak in operation, the wearer inhales previously exhaled breath and not the harmful atmosphere.

This admission of leakage demonstrates that the flap droops away from the seal surface.

Applicants are not aware of any other way in which the flap could leak.

Thirdly, Simpson shows the valve 12 on the top portion of the filtering face piece. In this position, the valve can take advantage of gravity to encourage the flap 15 to remain pressed against the seal surface when a wearer is neither inhaling nor exhaling. If a wearer tips their head downward, however, the advantage of gravity would be lost, and the flap could then droop away from the seal surface.

Previously submitted Affidavits of Dave Castiglione (Exhibit A) and of John Bowers (Exhibit B) both support the position that Simpson's valve could allow for the influx of contaminants because the flap is not pressed against the seal surface when a neutral position. For ease of reference, applicants have reproduced paragraph 9 of the Castiglione Affidavit:

9. That I do not agree with the position taken by the Examiner at the bottom of page 3 of the Office Action. My review of the '516 UK patent application leads me to the conclusion that the valve 13 shown in Figure 2 does not have its flap 15

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pressed towards the seal surface in an abutting relationship when the wearer is neither inhaling or exhaling. The '516 application reveals two distinctly different valves: a flap valve 13 as shown in Figure 2; and a diaphragm valve 14 as shown in Figure 3. These flaps have distinctly different constructions and operate differently. The [flapper] valve shown in Figure 2 has a flat seal surface. The mounting of the flap 15 to the seal surface at the top or fixed portion of the flap does not show a preload on the flap 15. There is nothing that can be discerned from Figure 2 or from the specification that would indicate that the flap is pressed towards the seal surface in its neutral position. And because Figure 3 shows a flap 18 resting upon the seal surface in the flap's neutral position while Figure 2 shows the flap 15 dangling away from the seal surface in an apparent neutral position also, it can be concluded that the valve 13 of Figure 2 would only become pressed against the seal surface during an inhalation. A review of the '516 UK application thus leads me to believe that the valve shown in Figure 2 is a unidirectional exhalation valve that prevents the influx of contaminants through the exhalation valve during an inhalation when it is most needed. It is not apparent to me that the valve would be pressed towards the seal surface under a neutral condition when the wearer is neither inhaling nor exhaling.

Applicants have also reproduced paragraphs 15 and 16 of the Bowers' Declaration:

15. My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

16. The Simpson product also has the valve located on the upper portion 1 of the pouch-shaped mask. This has the disadvantage that the warm moist exhaled air may be directed towards the eyes, causing misting of the eyewear. And Simpson's Fig. 2 valve cannot be positioned on the underside of the mask because the flap 15 would droop away from contact with the valve seat, causing the valve to leak.

As this testimony reveals, there is no mechanical means for having Simpson's flap 15 pressed against the seal surface. The Bowers' Declaration, in particular, states how the flap could droop away from the seal surface. It is improper for the Examiner to substitute his judgment for that of an expert in the field.<sup>1</sup> The Manual of Patent Examining Procedure explains:

<sup>1</sup> See, *In re Zeidler*, 215 USPQ 490 (CCPA 1982) ("Although perception of color may, in essence, be a 'subjective' determination, we believe that an expert's evaluation in this field is entitled to more weight than that of a layman. *In re Neave*, 54 CCPA 999, 1007, 370 F.2d 961, 968, 152 USPQ 274, 279-80 (1967) ("Therefore, because the

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Evidence traversing rejections must be considered by the Examiner whenever present. All entered affidavits, declarations, and other evidence traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action....*Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient.* General statements such as 'the declaration lacks technical validity' or 'the evidence is not commensurate with the scope of the claims' without an explanation supporting such findings are insufficient (emphasis added).<sup>2</sup>

Despite the explicit language in the MPEP highlighted above, the Examiner has yet to explain why the evidence furnished by applicants is insufficient. The Examiner only comments on what the Simpson patent does not disclose (and as indicated above, does so erroneously).

**2. Examiner's Answer at paragraph bridging pages 9 and 10**

"On the contrary, Simpson et al. fig. 3 clearly illustrates a valve flap (14) being resiliently held in a closed position against knife edge sealing surface (19) thereby providing a clear teaching of a seal between the valve flap and valve seat during before the mask is donned."

**Applicants' Response:**

The Figure 3 valve in Simpson is a centrally-mounted, button-style valve. These valves are distinctly different in structure and function from the non-centrally mounted flapper-style or cantilevered valves, see Fig. 2 of Simpson. Further, even if the Figure 3 valve was a flapper-style valve, there is no evidence that the flap in Fig. 3 is pressed against the seal surface.

**3. Examiner's Answer at page 10, sentence beginning at line 5**

"Further, Simpson et al. (page 1, lines 39-64 and page 2, lines 29-32) disclose that the mask is intended to filter harmful vapors (a function which cannot be accomplished while an exhalation valve is dangling open), that the mask includes an exhalation valve(s) located on portion (1, upper side) and/or portion (2, lower side) of the mask, that the exhalation valve(s) are

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qualifications of Lach and the test procedures which he employed are unchallenged, the board's holding that 'a more dramatic difference in results' is required constitutes reversible error, the board having erroneously substituted its judgment for that of an established expert in the art."); *In re Fay*, 146 USPQ 47 (CCPA 1965) ("It seems to us that one as well qualified in the highly technical art of fluoride-containing halogenated compounds as Henne is shown to be is properly entitled to express his expert opinion, and that such an opinion is entitled to be given consideration with the other evidence in the case in determining whether the conclusion of obviousness is supported by the opinion of the examiner as to what the prior art teaches. For the reasons previously stated we do not think the prior art teachings furnish factual support for the examiner's opinion."); see also *In re Alton*, 37 USPQ2d 1578 (Fed. Cir. 1996) ("We do, however, hold that the examiner's final rejection and Answer contained two errors; (1) viewing the Wall declaration as opinion evidence addressing a question of law rather than a question of fact; and (2) the summary dismissal of the declaration, without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case of inadequate description.").

<sup>2</sup> MANUAL OF PATENT EXAMINING Procedure § 2144.03, 2100-129 (August 2001).

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intended to materially reduce the buildup of water vapor and that while the exhalation valve(s) may leak it is clear from the disclosure that they are not intended to leak. Therefore, in view of the the disclosure as a whole, one of ordinary skill could not conclude that the exhalation valve(s) of Simpson et al. would require negative inhalation pressure in order to remain in a closed position."

**Applicants' Response:**

The Examiner seems to be reviewing the Simpson patent from the perspective of the person who has read specification of applicants' invention rather than from the state-of-the-art that existed at the time the Simpson patent was published. Because Simpson (i) does not impose a preload on its flapper valve 13 shown Figure 2 and because Simpson (ii) places the valve 12 on the top portion 1 of the mask (figure 1) and (iii) suggests the use of an antechamber to prevent harmful contaminants from leaking into the mask through the exhalation valve, it is clear that the Simpson valve does not remain closed under any orientation of the mask. Thus, although it may be apparent that a person of ordinary skill would want to design a flapper valve that remained closed under all conditions after reading applicants' specification, it certainly was not apparent to Simpson in 1980. While the Examiner asserts that "one of ordinary skill could conclude" that such a valve would have been created in the Simpson disclosure, the record does not reflect any evidence of this. Indeed, the record reflects the exact opposite. The Examiner's reasoning thus does not appear to derive from Simpson but rather is a viewpoint that was arrived at after reading present specification.

**4. Examiner's Answer at page 10, first full paragraph**

"Applicant's assertion that the exhalation valve flap would dangle open responsive to gravitational forces even if accurate does not distinguish from Simpson et al. because if the exhalation valve of fig. 2 were located within portion #1 (upper portion) of the mask as illustrated in fig. 1 and as disclosed by Simpson et al. at page 2, lines 29-32, then by applicant's own reasoning the valve flap would remain in the closed position due to gravitational forces until being subjected to the pressure of exhalation by a wearer."

**Applicants' Response:**

So what if Simpson's valve remains closed "due to gravitational forces until being subjected to the pressure of exhalation by a wearer"? Applicants do not claim a valve that is

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closed under only one particular orientation. Applicants' claims state that the valve can be held in its closed state "under any orientation of the valve." Further, applicants' claims state that this ability to remain closed stems "at least in part, by virtue of the [valve's] curved profile." Simpson's valve does not remain closed under any orientation, and even if it did, it would not do so by virtue of the valve's curved profile. The Simpson flap is not curved, and it only remains closed as a result of gravity when donned in an upright position.

**5. Examiner's Answer at paragraph bridging pp. 10 and 11**

"The Affidavit of David M. Castiglione is insufficient to overcome the above prior art rejection because: the declaration provides no objective evidence that the valve of fig.2 of Simpson et al. cannot remain closed without negative pressure within the mask based upon an actual physical inspection and comparison of the prior art device (Simpson et al.) to the device of the instant invention as claimed. Affiant concludes that the valve of fig.2 requires negative pressure within the mask in order to remain closed based upon a reading of the specification of Simpson et al. rather than on actual objective testing of the prior art device."

**Applicants' Response:**

Applicants submit that the Examiner has again committed legal error by disregarding the testimony of an expert. There is no need for a physical test when an expert can readily ascertain the structural and functional relationship between the flap and the valve seat by viewing the drawings and reading the description. The Examiner has not demonstrated otherwise. Further, the burden is not upon applicants to produce a physical test when the record already establishes that Simpson's flap is not pressed towards the seal surface under any orientation of the valve. Even without the testimony of Castiglione and Bowers, it is apparent, simply from looking at Figure 2, that Simpson's flexible flap is not positioned on the flap seat such that it is pressed towards the seal surface in an abutting relationship with it under any orientation of the valve. Consequently, the affidavits could more properly be characterized as being "overkill" rather than being "insufficient".

**6. Examiner's Answer at page 11, first full paragraph**

"As to the Bowers, Fabin, Castiglione and Betts affidavits, the individual arguments that McKim constitutes nonanalogous art because it has been held that a prior art reference must

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either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, it is submitted that one of ordinary skill would look to the art of valves (which includes McKim ('618)) to address problems associated with the effectiveness of valve seating of a valve element which is sued for controlling the direction of flow of breathable air through such a valve. McKim clearly addresses the problem of effectiveness of valve seating by non-aligning the flap retaining surface and the seal surface relative to each other thereby providing effective seating without float or bounce after each opening (col.1, lines 64-72)."

**Applicants' Response:**

The Examiner is misapplying the law. And is mischaracterizing the record. As indicated in applicants' Appeal Brief, the Examiner needs to consider the purposes of both the reference disclosure and the invention in determining whether the reference is reasonably pertinent to the particular problem that confronted the inventor.<sup>3</sup> In asserting that McKim is analogous to the invention claimed on appeal, the Examiner only looks at the purpose of the McKim patent. In this instance, the Examiner correctly states that McKim addresses the problem of effectiveness of valve seating without float or bounce after each opening. This purpose, however, is not the purpose of the present invention. In fact, it has no bearing on the present invention because problems of float or bounce do not exist in the exhalation valve art. This fact has been clearly established by the Bowers' Declaration. Bowers states that "under the airflows and pressure drops that are encountered in the filtering face mask, 'bounce or float' is not an occurring event or problem that investigators in the exhalation valve art need to deal with." Thus, the Examiner has mischaracterized the record by holding that persons of ordinary skill would modify known exhalation valves to deal with float or bounce problems.

**7. Examiner's Answer at paragraph bridging pp. 11 and 12**

"Applicant's argument that the McKim lacks the required flexibility of applicant's invention is noted; however, it is submitted that the valve of Simpson et al., being an exhalation valve, exhibits structure which is fully capable of providing such a function. Further, no

<sup>3</sup> *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1982).



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particular degree of flexibility is quantitatively and/or structurally defined in any of the claims of the instant application."

**Applicants' Response:**

Applicants have defined the term flexible to mean that the flap can "deform or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation" (p. 7, lines 22-24). Thus, it is incorrect to say that no degree of flexibility is quantitatively defined. As the Board is aware, claims must be interpreted in light of the specification and definitions set forth therein. Claims are not given simply the broadest construction possible but rather the broadest reasonable interpretation consistent with the specification.<sup>4</sup>

McKim clearly uses a mechanical means to cause its valve reed 14 to be bent. The force that McKim uses, as described by Betts, is on orders of magnitude greater than the forces that are used to bend flexible flaps in exhalation valves. If the McKim valve could bend so easily, its 2-cycle engine would be inoperative. When the meaning of applicants' term "flexible flap" is given an interpretation that is not just the broadest construction possible but is instead the broadest *reasonable* interpretation, *consistent* with the specification, as required by law, there can be no other conclusion other than that McKim's valve reed 14 would not qualify as a flexible flap.

**8. Examiner's Answer at paragraph bridging pp. 12 and 13**

"Applicant's assertions that the valve of fig.2 of Simpson et al. dangles open are not persuasive. The mask of Simpson et al. is specifically intended to filter gaseous or vaporous contaminants and particulate contaminants (page 1, lines 16-28 and lines 79-84) and is intended for use in noxious atmospheres (page 1, lines 58+). The valve of fig.2 is expressly disclosed as opening responsive to a wearer's exhalation (page 2, lines 38-50). One of ordinary skill would not conclude that the exhalation valve of fig.2 would dangle open under any conditions of proper use because the mask would not function as it is disclosed and intended to operate."

<sup>4</sup> *In re Reuter*, 651 F.2d 751, 210 USPQ 249, 253 (CCPA 1981); *In re Sneed*, 710 F.2d 1544, 218 USPQ 385, 388 (Fed. Cir. 1983).

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Applicants' Response:

This is an incorrect assessment of the scope and content of Simpson. See applicant's response above under paragraphs 1 and 3.

9. Examiner's Answer at page 13, 5<sup>th</sup> full paragraph

"As to appellants' argument that McKim is non-analogous art, it is submitted that one of ordinary skill would look to the art of valves (which includes McKim ('618)) to address problems associated with the effectiveness of valve seating of a valve element which is used for controlling the direction of flow of breathable air through such a valve. McKim clearly addresses the problem of effectiveness of valve seating by non-aligning the flap retaining surface and the seal surface relative to each other thereby providing effective seating without float or bounce after each opening (col.1, lines 64-72)."

Applicants' Response:

See applicants' response under paragraph 6.

10. Examiner's Answer at paragraph bridging pp. 13 and 14

"As to appellants' argument that the valve flap of McKim is not flexible, it is submitted that the valve flap of McKim exhibits flexibility (e.g. figs.1 and 3)."

Applicants' Response:

McKim may exhibit flexibility, but McKim's reed valve is not "flexible" as that term has been defined by applicants. Applicants' flap needs to bend in response to gravitational or exhalation fluid forces. McKim's reed valve does not so bend or flex. In fact, the McKim valve would be inoperative in applicants' invention. This is further evidence of why McKim resides in a non-analogous art and why a person of ordinary skill would not be motivated to apply McKim's teachings to the exhalation valve art.

Any interpretation of McKim that would have its valve reed 14 qualify as a "flexible flap" would either be the result of an incorrect reading of the scope and content of McKim or an overbroad unreasonable interpretation of the term "flexible flap" in the present case. The record shows that McKim's valve reed 14 "of sheet material, such as, for example, shim stock" would not be able to bend in response to gravity or breath from a person. As such, the McKim reed valve would be inoperable in applicants' invention. And the function of it and its problems of

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operation in a 2-cycle engine cannot be so easily applied to the respiratory mask art. It is true that the McKim flap does exhibit "flexibility" under another construction of this term. Applicants, however, have not defined the term "flexible" to be so broad as to encompass shim stock that does not bend in response to the force of gravity or a wearer's exhalate. McKim may illustrate in its figs. 1 and 3 that its valve reed can be bent, but this bending is done in response to a strong external mechanical force. Thus, unless the Examiner can supply the record with evidence to demonstrate otherwise, it would appear that the Examiner is either improperly interpreting McKim or is giving an unreasonable interpretation of the meaning of the term "flexible flap".

McKim may illustrate in its figs. 1 and 3 that its valve reed can be bent, but this illustration does not mean that the reed valve 14 in McKim qualifies as a "flexible flap" as that term would be reasonably interpreted by a person of ordinary skill, consistent with a reading of applicants' specification. As explained above, any interpretation of McKim, which would have its valve reed 14 qualify as a flexible flap, would either be the result of an incorrect reading of the scope and content of McKim or an overbroad unreasonable interpretation of the term "flexible flap". The record shows that McKim's valve reed 14 "of sheet material, such as, for example, shim stock" would not be able to be bent in response to gravity from the breath of a person.<sup>5</sup> Unless the Examiner can supply the record with evidence to demonstrate otherwise, the Examiner must be giving an unreasonable construction to the meaning of "flexible flap".

**11. Examiner's Answer at page 14, first full paragraph**

"Appellants' argument that the record lacks evidence to combine teachings of Simpson et al. with McKim is not accurate. As stated herein above in the body of the rejection, it would have been obvious to modify the exhalation valve of Simpson et al. to be mounted to the valve seat such that the one free portion (opposite the fixed portion #14a as illustrated in fig.3 of McKim) of the flap exhibits a curvature when viewed from the side and is pressed towards the seal surface in an abutting relationship with it when a fluid is not passing through the orifice for because it would have provided for seating quickly, effectively and without float or bounce after each opening as taught by McKim."

<sup>5</sup> See Richard Betts' Declaration.

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Applicants' Response:

The record does not contain any evidence that exhalation valves exhibit float or bounce problems. Indeed, the record establishes the exact opposite. The Examiner's unsupported view is not evidence that would support a proper combination of references.

McKim improves the efficiency of the seal by eliminating float or bounce, which occurs when a 2-cycle gasoline engine operates at high rpms. The record clearly establishes that float or bounce is not a problem that is encountered in the field of exhalation valves for filtering face masks. There is therefore no lack of efficiency that could stem from this problem. Thus, the reason that is cited by the Examiner for making the asserted combination simply is nonexistent in this record. The Examiner has accordingly committed legal error by using a fabricated reason for making the combination.

As applicants have demonstrated repeatedly in this prosecution, persons skilled in the art of designing exhalation valves do not search for solutions to eliminating float or bounce. Applicants have supported this position with uncontroverted documentary evidence in the form of Affidavits and Declarations signed by persons skilled in the field of designing such valves. The record also is devoid of a single reference that states, either explicitly or implicitly, that exhalation valves exhibit float or bounce problems. Because applicants have fully established that persons who design exhalation valves do not encounter — much less look for solutions to — "float or bounce" problems, the record accordingly lacks any motivating evidence for making the combination asserted in the rejection. Nonetheless, the Examiner maintains the position that a person skilled in the art of designing exhalation valves would have used the teachings of McKim's gasoline engine reed valve for purposes of eliminating float or bounce in an exhalation valve despite no evidentiary authority in the record, other than mere opinion.<sup>6</sup> As the Board is aware, bald conclusions like this are not *evidence* that can be properly relied on to sustain a rejection based on a combination of references.<sup>7</sup>

<sup>6</sup> "Unsupported" is probably not the best word to use in this sentence. The Examiner's view is not merely "unsupported": it is actually "false". This falsity has been established by Bowers and Fabin when they unequivocally stated that float or bounce is not a problem that is confronted by persons who design exhalation valves. <sup>7</sup> See, *In re Dembiczak*, 50 USPQ 1614, 1617 (Fed. Cir. 1999) ("Broad conclusory statements regarding the teachings of multiple references, standing alone, are not 'evidence.'"); See also, *Lee*, 61 USPQ2d at 1434 ("With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that 'the demonstration mode is just a programmable feature which can be used in many different device(s) for providing automatic introduction by adding the proper programming software' and that 'another motivation' would be that the automatic demonstration mode is user friendly and it functions as a 'tutorial' do

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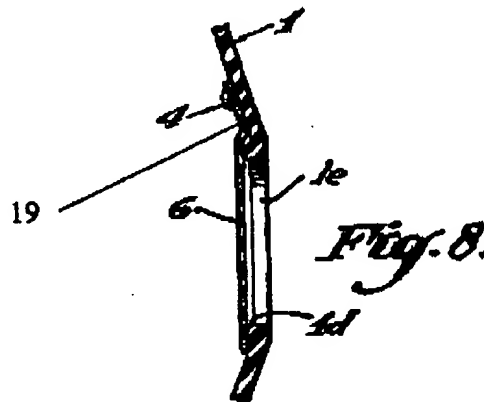
**12. Examiner's Answer at page 14, second full paragraph**

"As to appellants' argument that "If the particular method necessary for causing the flap to be pressed towards the seal surface would have been obvious to a person of ordinary skill in making a flapper-style exhalation valve, you would have expected a person skilled in the exhalation valve art to have used that technology in a valve like Simpson's.", it is submitted that an example of such an exhalation valve is taught in the prior art to Matheson (cited but not applied) U.S. Patent 2,999,498 at col. 1, lines 38-46."

**Applicants' Response:**

The Examiner's position is inaccurate: the scope and content of the prior art have again been mischaracterized.

Matheson (U.S. 2,999,498) describes an inhalation valve, not an exhalation valve. And there is no disclosure in Matheson, which disclosure shows that its flap is biased towards the seal surface. In fact, Matheson teaches the opposite. Figure 8 of Matheson is reproduced below for ease of reference.



As shown, the Matheson valve has a "kink" in it at the location identified by applicants' attorney using numeral 19. This "kinked" portion would not cause the free portion of the flap to be pressed towards the seal surface so that it could reside closed under any orientation of the valve. Indeed, Matheson realizes this by indicating that its valve requires gravity to keep the flap closed:

not adequately address the issue of motivation to combine. The factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority.").

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An important feature of suspending diaphragms 6 and 7 from the top only without further support along the marginal portions is that gravity will assist in keeping the diaphragms in their normal downward and seated positions as shown in Fig. 8.<sup>8</sup>

Further, inhalation valves, unlike exhalation valves, close during an exhalation in response to the exhalation pressure. And air that passes through the inhalation valve must first pass through the filter media in the filter cartridge. Therefore, there is no need to place a pre-stress on the valve to keep it closed under any orientation of the mask. The inhalation valve closes forcibly when a wearer exhales (see the '498 patent to Matheson at column 4, lines 1-8) so that the exhaled air is quickly forced out of the exhalation valve rather than through the filter media.

**13. Examiner's Answer at page 15, first full paragraph**

"Finally, the question of whether McKim constitutes non-analogous art has been addressed and settled in a previous appeal to the Board of Appeals in appellants' related application 08/240,877 in which the Board of Appeals upheld the prior art combination of McKim with other prior art references including Simpson et al. For the above reasons, it is believed that the rejections should be sustained."

**Applicants' Response:**

Once again the Examiner has mischaracterized the record. The Board of Patent Appeals and Interferences has never dealt with the issue of whether McKim constitutes non-analogous art. That issue was never raised in application 08/240,877. Therefore, it was never decided. Applicants never argued that McKim was non-analogous art, and the Board made no reference to the issue in their decision. Further, the claims that were present in 08/240,877 are distinctly different from the claims that are present on appeal in this case. In addition, the evidence presented in the Castiglione, Bowers, Fabin, and Betts' Declarations were not of record in the '877 case. In short, the issue was never presented, never decided, and even if it was, it would not be pertinent to the present case because the claims are different and additional evidence is now of record.

<sup>8</sup> See the '498 patent to Matheson at column 2, lines 53-57.

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For the reasons submitted above and those presented in their Appeal Brief, applicants believe that the decision below should be reversed.

Respectfully submitted,

December 2, 2003

Date

By: 

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